File 11-10-92

DP Barcode : D181410
PC Code No : 113201
EEB Out : NOV 10 1992

To: Bruce Sidwell
Product Manager 53
Special Review and Reregistration Division (H7508W)

From: Douglas J. Urban, Acting Chief
Ecological Effects Branch/EFED (H7507C)

Attached, please find the EEB review of...

Reg./File # : 113201-007969
Chemical Name : Vinclozolin
Type Product : Fungicide
Product Name :
Company Name : BASF Corporation
Purpose : Review of Tier 1 aquatic plant studies for reregistration.

Action Code : 627 Date Due : 12/08/92
Reviewer : Tracy Perry

EEB Guideline/MRID Summary Table: The review in this package contains an evaluation of the following:

GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT	GDLN NO	MRID NO	CAT
71-1(A)			72-2(A)			72-7(A)		
71-1(B)			72-2(B)			72-7(B)		
71-2(A)			72-3(A)			122-1(A)		
71-2(B)			72-3(B)			122-1(B)		
71-3			72-3(C)			122-2	42394701 42394702 42394703 42394704 42394705	Y Y Y Y Y
71-4(A)			72-3(D)			123-1(A)		
71-4(B)			72-3(E)			123-1(B)		
71-5(A)			72-3(F)			123-2		
71-5(B)			72-4(A)			124-1		
72-1(A)			72-4(B)			124-2		
72-1(B)			72-5			141-1		
72-1(C)			72-6			141-2		
72-1(D)						141-5		

Y=Acceptable (Study satisfied Guideline)/Concur
P=Partial (Study partially fulfilled Guideline but additional information is needed

DP BARCODE: D181410 REREG CASE #2740

CASE: 816411 DATA PACKAGE RECORD DATE: 08/10/92
SUBMISSION: S422209 BEAN SHEET Page 1 of 1

* * * CASE/SUBMISSION INFORMATION * * *

CASE TYPE: REREGISTRATION ACTION: 627 GENERIC DATA SUBMISSION
CHEMICALS: 113201 Vinclozolin 100.00 %

ID#: 113201-007969
COMPANY: 007969 BASF CORPORATION
PRODUCT MANAGER: 53 BRUCE SIDWELL 703-308-8078 ROOM: CS1 3E3
PM TEAM REVIEWER: MARGARITA COLLANTES 703-308-8583 ROOM: CS1 34J1
RECEIVED DATE: 07/10/92 DUE OUT DATE: 11/07/92

* * * DATA PACKAGE INFORMATION * * *

DP BARCODE: 181410 EXPEDITE: N DATE SENT: 08/10/92 DATE RET.: / /
CHEMICAL: 113201 Vinclozolin
DP TYPE: 999 Miscellaneous Data Package
ADMIN DUE DATE: 12/08/92 CSF: N LABEL: N

ASSIGNED TO	DATE IN	DATE OUT
DIV : EFED	08/11/92	/ /
BRAN: EEB	08/11/92	/ /
SECT:	/ /	/ /
REVR :	/ /	/ /
CONTR:	/ /	/ /

* * * DATA REVIEW INSTRUCTIONS * * *

Please review the attached documents submitted to the Agency in support of reregistration:

MRID	GDLN
42394701	122-2
42394702	"
42394703	"
42394704	"
42394705	"

* * * ADDITIONAL DATA PACKAGES FOR THIS SUBMISSION * * *

DP BC	BRANCH/SECTION	DATE OUT	DUE BACK	INS	CSF	LABEL
180847	OREB	07/22/92	11/19/92	Y	N	N
180848	EFGB	07/22/92	11/19/92	Y	N	N

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES
AND TOXIC SUBSTANCES

NOV 10 1992

MEMORANDUM

SUBJECT: Vinclozolin: review of Tier 1 aquatic plant studies for reregistration.

FROM: Douglas Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

Douglas J. Urban 11/9/92

TO: Bruce Sidwell, PM 53
Reregistration Branch
Special Review and Reregistration Division (H7508C)

As part of the reregistration process for vinclozolin, the registrant, BASF Corporation, has submitted the following Tier 1 aquatic plant studies for review:

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Selenastrum capricoruntum. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-01.

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Anabaena flos-aquae. Laboratory Project ID No. B445-12-2. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-02.

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Navicula pelliculosa. Laboratory Project ID No. B445-12-3. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-03.

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Skeletonema costatum. Laboratory Project ID No. B445-12-4. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-04.

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Lemna gibba G3. Laboratory Project ID No. B445-12-5. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-05.

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MEMORANDUM

SUBJECT: Vinclozolin: review of Tier 1 aquatic plant studies for reregistration.

FROM: Douglas Urban, Acting Branch Chief
Ecological Effects Branch
Environmental Fate and Effects Division (H7507C)

TO: Bruce Sidwell, PM 53
Reregistration Branch
Special Review and Reregistration Division (H7508C)

As part of the reregistration process for vinclozolin, the registrant, BASF Corporation, has submitted the following Tier 1 aquatic plant studies for review:

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Selenastrum capricoruntum. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-01.

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Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Navicula pelliculosa. Laboratory Project ID No. B445-12-3. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-03.

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Skeletonema costatum. Laboratory Project ID No. B445-12-4. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-04.

Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to Lemna gibba G3. Laboratory Project ID No. B445-12-5. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. MRID No. 423947-05.

CONCURRENCES

SYMBOL	H7507C	H7507C	H-7507C					
SURNAME	S. Perry	Cm	D. Urban					
DATE	10/3/92	11/3/92	11/9/92					

EPA Form 1320-1 (12-70) OFFICIAL FILE COPY

EEB has reviewed these studies and classified them as core. Therefore, the guideline requirement 122-2 Tier 1 Aquatic Plant Growth has been satisfied. Since the aquatic species tested at the Tier 1 level exhibited less than a 50% detrimental effect as compared to the control, Tier 2 aquatic plant testing is not required. Please find all applicable data requirements for vinclozolin and their statuses in the attached table.

If you have any questions, please contact Tracy Perry at 305-6451 or Henry Craven at 305-5320.

Date: 11/02/92
Case No: 816411
Chemical No: 113201

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
6 Basic Studies in Bold					
71-1(a) Acute Avian Oral, Quail/Duck	(TGAI)	A	YES	Fink 1978	NO
71-1(b) Acute Avian Oral, Quail/Duck	(TEP)	-	-	-	-
71-2(a) Acute Avian Diet, Quail	(TGAI)	A	YES	Fink 1978	NO
71-2(b) Acute Avian Diet, Duck	(TGAI)	A	YES	Fink 1978	NO
71-3 Wild Mammal Toxicity	(TGAI)	-	-	-	-
71-4(a) Avian Reproduction Quail	(TGAI)	A	NO	070698 [3]	YES
71-4(b) Avian Reproduction Duck	(TGAI)	A	NO	070698 [3]	YES
71-5(a) Simulated Terrestrial Field Study	(TEP)	-	-	-	-
71-5(b) Actual Terrestrial Field Study	(TEP)	-	-	-	-
72-1(a) Acute Fish Toxicity Bluegill	(TGAI)	A	YES	264302	NO
72-1(b) Acute Fish Toxicity Bluegill	(TEP)	-	-	-	-
72-1(c) Acute Fish Toxicity Rainbow Trout	(TGAI)	A	NO	264302 [4]	YES
72-1(d) Acute Fish Toxicity Rainbow Trout	(TEP)	-	-	-	-
72-2(a) Acute Aquatic Invertebrate Toxicity	(TGAI)	A	YES	Union Carbide 1978	NO
72-2(b) Acute Aquatic Invertebrate Toxicity	(TEP)	-	-	-	-
72-3(a) Acute Estu/Mari Tox Fish	(TGAI)	-	-	-	-
72-3(b) Acute Estu/Mari Tox Mollusk	(TGAI)	-	-	-	-
72-3(c) Acute Estu.Mari Tox Shrimp	(TGAI)	-	-	-	-

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* In Bibliographic Citation column indicates study may be upgradeable

Date: 11/02/92
Case No: 816411
Chemical No: 113201

PHASE IV
DATA REQUIREMENTS FOR
ECOLOGICAL EFFECTS BRANCH

Data Requirements	Composition [1]	Use Pattern [2]	Does EPA Have Data To Satisfy This Requirement? (Yes, No)	Bibliographic Citation	Must Additional Data Be Submitted under FIFRA3(c)(2)(B)?
72-3(d) Acute Estu/Mari Tox Fish	(TEP)	-	-	-	-
72-3(e) Acute Estu/Mari Tox Mollusk	(TEP)	-	-	-	-
72-3(f) Acute Estu/Mari Tox Shrimp	(TEP)	-	-	-	-
72-4(a) Early Life-Stage Fish	(TGAI)	-	-	-	-
72-4(b) Live-Cycle Aquatic Invertebrate	(TGAI)	-	-	-	-
72-5 Life-Cycle Fish	(TGAI)	-	-	-	-
72-6 Aquatic Org. Accumulation	(TGAI)	-	-	-	-
72-7(a) Simulated Aquatic Field Study	(TEP)	-	-	-	-
72-7(b) Actual Aquatic Field Study	(TEP)	-	-	-	-
122-1(a) Seed Germ./Seedling Emerg.	(TGAI)	-	-	-	-
122-1(b) Vegetative Vigor	(TGAI)	-	-	-	-
122-2 Aquatic Plant Growth	(TGAI)	A	YES	423947-(01-05)	NO
123-1(a) Seed Germ./Seedling Emerg.	(TGAI)	-	-	-	-
123-1(b) Vegetative Vigor	(TGAI)	-	-	-	-
123-2 Aquatic Plant Growth	(TGAI)	-	-	-	-
124-1 Terrestrial Field Study	(TEP)	-	-	-	-
124-2 Aquatic Field Study	(TEP)	-	-	-	-
141-1 Honey Bee Acute Contact	(TGAI)	A	YES	40992801	NO
141-2 Honey Bee Residue on Foliage	(TEP)	-	-	-	-
141-5 Field Test for Pollinators	(TEP)	-	-	-	-

* In Bibliographic Citation column indicates study may be upgradeable

1.Composition: TGAI=Technical grade of the active ingredient; PAIRA=Pure active ingredient, radiolabeled; TEP=Typical end-use product

2.Use Patterns: A=Terrestrial Food Crop; B=Terrestrial Feed Crop; C=Terrestrial Non-Food Crop; D=Aquatic Food Crop; E=Aquatic Non-Food Outdoor; F=Aquatic Non-Food Industrial; G=Aquatic Non-Food Residential; H=Greenhouse Food Crop; I=Greenhouse Non-Food Crop; J=Forestry; K=Outdoor Residential; L=Indoor Food; M=Indoor Non-Food; N=Indoor Medical; O=Indoor Residential; Z=Use Group for Site 00000

3. This study was found to be scientifically sound but does not fulfill data requirements as the EECs exceed the highest concentration tested (50 ppm). This study needs to be repeated.

4. This study was classified as supplemental as the test temperature was too high; the registrant has agreed to repeat the study at a lower temperature.

File

MRID No. 423947-01

DATA EVALUATION RECORD

1. **CHEMICAL:** Vinclozolin.
Shaughnessey No. 113201.

2. **TEST MATERIAL:** Vinclozolin (BAS 352 F); 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione; Lot No. N176; CAS No. 50471-44-8; 98.0% active ingredient; a white powder.

3. **STUDY TYPE:** 122-2. Growth and Reproduction of Aquatic Plants - Tier 1. Species tested: *Selenastrum capricoruntum*.

4. **CITATION:** Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to *Selenastrum capricoruntum*. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. Study ID No. B445-12-1. Submitted by BASF Corporation, Agricultural Chemicals, Research Triangle Park, NC. EPA MRID No. 423947-01.

5. **REVIEWED BY:**

Charles G. Nace Jr.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Charles G Nace Jr.
Date: 09/22/92

6. **APPROVED BY:**

Mark Mossler, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: [signature]
Date: 9/22/92

Harry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: H. T. Craven
Date: 11/3/92

Tracy L. Perry 10/29/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guidelines for a Tier 1 non-target growth and reproduction study using aquatic plants. Vinclozolin at a measured concentration of 1.02 mg ai/l reduced the growth of *S. capricornutum* by 1.2%.

8. **RECOMMENDATIONS:** N/A

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

6.0

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11. **MATERIALS AND METHODS:**

A. **Test Species:** An in-house, seven-day old culture of *Selenastrum capricornutum* was used in this study. The original culture came from the University of Texas Culture Collection (UTEX #1648). Stock cultures were maintained in synthetic algal assay procedure (AAP) nutrient medium in Erlenmeyer flasks under 4306 lux at a temperature of 24 ±2°C.

B. **Test System:** The testing was carried out in 500 ml Erlenmeyer flasks fitted with foam stoppers to permit gas exchange. Each flask contained 100 ml of test solution and was placed in an incubator shaker which was set at 100 oscillations per minute. The test organisms were exposed to continuous, cool-white fluorescent light, with an intensity of 4306 ±646 lux. The temperature was maintained at 24 ±2°C.

A stock solution was made by dissolving 127.6 mg of vinclozolin in 25 ml of N-N-dimethylformamide (DMF). The test solution was prepared by adding 0.2 ml of the stock solution to AAP medium (pH 7.5, 0.22 mm filtered), which was brought to the volume of 1 l.

C. **Dosage:** Five-day static test. One nominal test concentration of 1 mg active ingredient (a.i.), a blank control, and a solvent control were used in the study. The blank control consisted of medium and the solvent blank contained 0.2 ml DMF per liter of medium. The maximum concentration of test material as applied to a six inch water column was reported to be 735 µg/l.

D. **Design:** The test concentration, blank control, and solvent control were replicated 3 times. The initial cell density was 3,000 cells/ml. The inoculum volume was 0.32 ml.

Cell densities were recorded with an electric particle counter on Days 3, 4, and 5. The pH was measured at initiation and termination of the test. The temperature was recorded continuously and measured manually daily. Flasks were randomly repositioned daily.

The actual concentration of test material in the test treatments on Day 0 and at test termination were determined.

E. **Statistics:** The growth in the test solutions were

compared that of the pooled control to determine if a significant reduction had occurred.

12. **REPORTED RESULTS**: The analytical results show the test solution had a concentration of 1.02 mg/l at test termination (Table 1, attached). A slight discrepancy was noted due to the Day 0 sample breaking during shipping and therefore only having a concentration of 0.55 mg/l. The stability samples and the Day 5 test solution samples both indicate that the amount vinclozolin in the test solutions was near the desired nominal concentration. The EC_{50} value is based on the mean measured concentration at Day 5.

Cell densities determined at each observation time are presented in Table 4 (attached). The percent inhibition of growth in the treatment solution was 1.2% compared with the pooled control group (Table 5, attached). Based on measured Day 5 concentrations, the 120-hour EC_{50} value was estimated to be greater than 1.02 mg/l.

The pH ranged from 7.62 to 7.71 at test initiation and from 8.06 to 8.17 at test termination.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES**: "Since less than 50% inhibition was observed at the test concentration, the EC_{50} is greater than 1.02 mg/l Vinclozolin. Thus, Tier 2 testing is not indicated."

Good Laboratory Practice and Quality Assurance Inspection statements were included in the report indicating compliance with EPA Good Laboratory Practice Standards, 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS**:

A. **Test Procedure**: The test procedure followed guidelines in the SEP and Subdivision J. There was one deviation from the recommended guidelines.

Cell counts were taken on Days 3, 4, and 5. Cell counts should be taken daily for an algal growth study.

B. **Statistical Analysis**: A visual inspection of the percent inhibition of growth in comparison to the pooled control yielded the same result as that determined by the authors.

C. **Discussion/Results**: This study is scientifically sound and meets the guidelines for a Tier 1 non-target growth

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and reproduction study using aquatic plants. Vinclozolin at a measured concentration of 1.02 mg ai/l reduced the growth of *Selenastrum capricoruntum* by 1.2%.

D. **Adequacy of the Study:**

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 09/01/92.

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RIN 5715-93

VINCLOZOLIN EEB REVIEWS

Page_____ is not included in this copy.

Pages 13 through 14 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

____ Sales or other commercial/financial information.

____ A draft product label.

____ The product confidential statement of formula.

____ Information about a pending registration action.

__✓__ FIFRA registration data.

____ The document is a duplicate of page(s) _____.

____ The document is not responsive to the request.

The information not included is generally considered confidential by product registrants. If you have any questions, please contact the individual who prepared the response to your request.

DATA EVALUATION RECORD

1. **CHEMICAL:** Vinclozolin.
Shaughnessey No. 113201.

2. **TEST MATERIAL:** Vinclozolin (BAS 352 F); 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione; CAS No. 50471-44-8; Lot No. N176; 98% active ingredient; a white powder.

3. **STUDY TYPE:** 122-2. Growth and Reproduction of Aquatic Plants - Tier 1. Species Tested: *Anabaena flos-aquae*.

4. **CITATION:** Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to *Anabaena flos-aquae*. Laboratory Project ID No. B445-12-2. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by BASF Corporation, Agricultural Chemicals, Research Triangle Park, NC. EPA MRID No. 423947-02.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Agronomist
KBN Engineering and
Applied Sciences, Inc.

Signature: [signature]
Date: 9/24/92

6. **APPROVED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
Applied Sciences, Inc.

Signature: Louis M Rifici
Date: 9/24/92

Henry T. Craven, M.S.
Supervisor, EEB/EFED
USEPA

Signature: H. T. Craven 11/3/92
Date: Tracy L. Perry 10/29/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a measured concentration of 1.01 mg ai/l stimulated the growth of *A. flos-aquae* by 3.9% over the 5-day test period.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Species:** The alga used in the test, *Anabaena flos-aquae*, came from laboratory stock cultures originally obtained from the American Type Culture Collection, Rockville, MD. Stock cultures were maintained in synthetic algal assay procedure nutrient medium (AAP) under 2152 lux illumination, and a temperature of 24 ±2°C. The cultures were manually shaken once per day. Transfers were made to provide logarithmically-growing cultures. The culture used as inoculum in this test had been transferred to fresh medium four days before test initiation.

B. **Test System:** All glassware was cleaned according to EPA methods and autoclaved before use. Test vessels used were 500-ml Erlenmeyer flasks fitted with foam stoppers which permitted gas exchange. The test medium was the same as that used for culturing with the pH adjusted to 7.5 ±0.1. The medium was filter sterilized (0.22 µm) prior to inoculation.

The test vessels were kept in an incubator with environmental conditions like those employed in culturing with continuous cool-white illumination (2153 ±323 lux).

A 5 mg active ingredient (ai)/ml stock solution was prepared by diluting 51 mg of the test material to 10 ml with dimethylformamide (DMF). The test solution was created by addition of an appropriate volume of the stock (0.2 ml) to 1 l of nutrient medium. The solvent control contained 0.2 ml of DMF/l of nutrient medium.

C. **Dosage:** Five-day growth and reproduction test. One nominal concentration of 1.0 mg ai/l, and a solvent and medium control were selected for the definitive test. The maximum application concentration was reported to be 735 µg/l if applied to a six-inch water column.

D. **Test Design:** One-hundred ml of the appropriate test or control solution were placed into each of three replicate flasks (3 per treatment level and the controls). A blank (not inoculated) test solution was also prepared for use as a stability sample at test termination.

An aliquot of an *Anabaena flos-aquae* culture was sonicated to reduce the length of the algal filaments. An inoculum of cells calculated to provide 3000 cells/ml was aseptically introduced into each flask. The inoculum volume was 0.26 ml per flask. The flasks were shaken and randomly repositioned each working day to minimize spatial differences in the incubator. Cell counts were performed using an electronic particle counter on test days 3, 4, and 5. Five-ml samples were removed from each flask and sonicated for approximately 5 minutes. Three counts per replicate were used on each counting day.

Temperature in the incubator was automatically measured continuously and manually measured daily. The pH was measured at test initiation (initial test solutions) and at termination (each replicate). Samples were taken at test initiation (initial solutions) and at termination (each replicate) for analysis of the test material by gas chromatography. Samples taken at termination were removed from the supernatant of the solutions after centrifuging for 4 minutes at a speed of 4000 rpm. Samples were frozen and sent to the study sponsor.

E. **Statistics:** The medium and solvent control data were pooled since a t-test indicated no significant difference between the two ($p \leq 0.05$). Percent inhibition of algal growth in the treatment solution was determined by comparison to the growth of the pooled control cultures.

12. **REPORTED RESULTS:** The initial sample vial of the exposure solution was broken when received at the analytical laboratory. The liquid sample retained in the sample bag was determined to have a concentration of vinclozolin of 0.55 mg/l. However, the results from the terminal and stability samples indicated that the test material was present at concentrations of 1.01 and 1.06 mg/l, respectively (Table 3, attached). The results are therefore based on the mean measured concentration of the day 5 samples (1.01 mg/l).

Cell counts and percent inhibition after five days are given in Tables 4 and 5 (attached). The test material stimulated the growth of *A. flos-aquae* by 3.9% at a mean measured concentration of 1.01 mg/l.

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The pH ranged from 7.51 to 7.61 in the test solution and the controls at test initiation. The pH values on day 5 ranged from 7.90 to 8.01.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors concluded that there is no need for Tier 2 testing because less than 50% inhibition was observed in the test.

Good Laboratory Practice and Quality Assurance statements were included in the report indicating compliance with EPA Good Laboratory Practice Standards, 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedure and the report were generally in accordance with the SEP and Subdivision J guidelines, except for the following deviations:

Cell growth measurements were not taken daily. Measurements were made on days 3, 4, and 5 only.

The results of the temperature measurements were not reported.

B. **Statistical Analysis:** Visual inspection of the percent inhibition of growth in comparison to the pooled control yielded the same result as determined by the authors.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a measured concentration of 1.01 mg ai/l stimulated the growth of *A. flos-aquae* by 3.9% over the 5-day test period.

D. **Adequacy of the Study:**

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 9-17-92.

RIN 5715-93

VINCLOZOLIN EEB REVIEWS

Page_____ is not included in this copy.

Pages 19 through 21 are not included.

The material not included contains the following type of information:

____ Identity of product inert ingredients.

____ Identity of product impurities.

____ Description of the product manufacturing process.

____ Description of quality control procedures.

____ Identity of the source of product ingredients.

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3. **STUDY TYPE:** 122-2. Growth and Reproduction of Aquatic Plants - Tier 1. Species Tested: *Navicula pelliculosa*.

4. **CITATION:** Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to *Navicula pelliculosa*. Laboratory Project ID No. B445-12-3. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by BASF Corporation, Agricultural Chemicals, Research Triangle Park, NC. EPA MRID No. 423947-03.

5. **REVIEWED BY:**

Mark A. Mossler, M.S.
Agronomist
KBN Engineering and
Applied Sciences, Inc.

Signature: Mark A. Mossler
Date: 9/24/92

6. **APPROVED BY:**

Louis M. Rifici, M.S.
Associate Scientist
KBN Engineering and
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Signature: Louis M. Rifici
Date: 9/24/92

Henry T. Craven, M.S.
Supervisor, EEB/EFED
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Signature: Henry T. Craven 11/3/92
Date: Tracy L. Perry 10/29/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a mean measured concentration of 1.06 mg ai/l stimulated the growth of *N. pelliculosa* by 94.5% over the 5-day test period.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

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10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Species:** The diatom used in the test, *Navicula pelliculosa*, came from laboratory stock cultures originally obtained from the University of Texas, Austin. Stock cultures were maintained in synthetic algal assay procedure nutrient medium with added silicon (AAP/Si) under 4306 lux illumination, and a temperature of 24 ±2°C. The flasks were continuously shaken and transfers were made to provide logarithmically-growing cultures. The culture used as inoculum in this test had been transferred to fresh medium seven days before test initiation.

B. **Test System:** All glassware was cleaned according to EPA methods and autoclaved before use. Test vessels used were 500-ml Erlenmeyer flasks fitted with foam stoppers which permitted gas exchange. The test medium was the same as that used for culturing with the pH adjusted to 7.5 ±0.1. The medium was filter sterilized (0.22 µm) prior to inoculation.

The test vessels were kept in an incubator with environmental conditions like those employed in culturing with continuous cool-white illumination (4306 ±646 lux).

A 5 mg active ingredient (ai)/ml stock solution was prepared by diluting 51 mg of the test material to 10 ml with dimethylformamide (DMF). The test solution was created by addition of an appropriate volume of the stock (0.2 ml) to 1 l of nutrient medium. The solvent control contained 0.2 ml of DMF/l of nutrient medium.

C. **Dosage:** Five-day growth and reproduction test. One nominal concentration of 1.0 mg ai/l, and a solvent and medium control were selected for the definitive test. The maximum application concentration was reported to be 735 µg/l if applied to a six-inch water column.

D. **Test Design:** One-hundred ml of the appropriate test or control solution were placed into each of four replicate flasks (4 per treatment level and the controls). A blank (not inoculated) test solution was also prepared to determine stability at test termination.

An aliquot of *Navicula pelliculosa* cells calculated to provide 3000 cells/ml was aseptically introduced into each flask. The inoculum volume was 0.5 ml per flask. The flasks were shaken continuously (100 rpm) and randomly repositioned each working day to minimize spatial differences in the incubator. Cell counts were performed using an electronic particle counter on test days 3, 4, and 5. Three counts per replicate were made on each counting day.

Temperature in the incubator was automatically measured continuously and manually measured daily. The pH was measured at test initiation (initial test solutions) and at termination (each replicate). Samples were taken at test initiation (initial solutions) and at termination (each replicate) for analysis of the test material by gas chromatography. Samples taken at termination were removed from the supernatant of the solutions after centrifuging for 4 minutes at a speed of 4000 rpm. Samples were frozen and sent to the study sponsor.

E. **Statistics:** The medium and solvent control data were pooled since a t-test indicated no significant difference between the two ($p \leq 0.05$). Percent inhibition of algal growth in the treatment solutions was determined by comparison to the growth of the pooled control cultures.

12. **REPORTED RESULTS:** Although there was a small amount of test material detected in the initial solvent control sample, this was believed to be an artifact as none of the material was present after 5 days. The results from the initial and terminal exposure samples indicated that the test material was present at concentrations of 1.04 and 1.07 mg/l, respectively (Table 3, attached). The results are therefore based on the mean measured concentration of these samples (1.06 mg/l).

Cell counts and percent inhibition after five days are given in Tables 4 and 5 (attached). The test material stimulated the growth of *N. pelliculosa* by 94.5% at a mean measured concentration of 1.06 mg/l.

The pH ranged from 7.51 to 7.61 in the test solution and the controls at test initiation. The pH values on day 5 ranged from 7.46 to 7.71.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors concluded that there is no need for Tier 2

testing because less than 50% inhibition was observed in the test.

Good Laboratory Practice and Quality Assurance statements were included in the report indicating compliance with EPA Good Laboratory Practice Standards, 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedure and the report were generally in accordance with the SEP and Subdivision J guidelines, except for the following deviations:

Cell growth measurements were not taken daily. Measurements were made on days 3, 4, and 5 only.

The results of the temperature measurements were not reported.

B. **Statistical Analysis:** Visual inspection of the percent inhibition of growth in comparison to the pooled control yielded the same result as determined by the authors.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a mean measured concentration of 1.06 mg ai/l stimulated the growth of *N. pelliculosa* by 94.5% over the 5-day test period.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 9-17-92.

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RIN 5715-93

VINCLOZOLIN EEB REVIEWS

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DATA EVALUATION RECORD

1. **CHEMICAL:** Vinclozolin.
Shaughnessey No. 113201.

2. **TEST MATERIAL:** Vinclozolin (BAS 352 F); 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione; CAS No. 50471-44-8; Lot No. N176; 98% active ingredient; a white powder.

3. **STUDY TYPE:** 122-2. Growth and Reproduction of Aquatic Plants - Tier 1. Species Tested: *Skeletonema costatum*.

4. **CITATION:** Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to *Skeletonema costatum*. Laboratory Project ID No. B445-12-4. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by BASF Corporation, Agricultural Chemicals, Research Triangle Park, NC. EPA MRID No. 423947-04.

5. **REVIEWED BY:**

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Agronomist
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Date: 9/24/92

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Supervisor, EEB/EFED
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Signature: Henry T. Craven
Date: 11/3/92

Tracy L. Perry 10/29/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a mean measured concentration of 0.87 mg ai/l inhibited the growth of *S. costatum* by 3.8% over the 5-day test period.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Species:** The diatom used in the test, *Skeletonema costatum*, came from laboratory stock cultures originally obtained from the EPA Environmental Research Laboratory in Gulf Breeze, FL. Stock cultures were maintained in synthetic marine algal assay nutrient medium (MAA) under 4306 lux illumination, and a temperature of 20 ±2°C. The flasks were shaken once a day and transfers were made to provide logarithmically-growing cultures. The culture used as inoculum in this test had been transferred to fresh medium seven days before test initiation.

B. **Test System:** All glassware was cleaned according to EPA methods and autoclaved before use. Test vessels used were 500-ml Erlenmeyer flasks fitted with foam stoppers which permitted gas exchange. The test medium was the same as that used for culturing with the pH adjusted to 8.1 ±0.1.

The test vessels were kept in an incubator with environmental conditions like those employed in culturing with a 14 hour photoperiod supplied by cool-white fluorescent illumination (2153 ±323 lux).

A 5 mg active ingredient (ai)/ml stock solution was prepared by diluting 51 mg of the test material to 10 ml with dimethylformamide (DMF). The test solution was created by addition of an appropriate volume of the stock (0.2 ml) to 1 l of nutrient medium. The solvent control contained 0.2 ml of DMF/l of nutrient medium.

C. **Dosage:** Five-day growth and reproduction test. One nominal concentration of 1.0 mg ai/l, and a solvent and medium control were selected for the definitive test. The maximum application concentration was reported to be 735 µg/l if applied to a six-inch water column.

D. **Test Design:** One-hundred ml of the appropriate test or control solution were placed into each of three replicate flasks (3 per treatment level and the controls). A blank (not inoculated) test solution was also prepared to determine stability at test termination.

An aliquot of *Skeletonema costatum* cells calculated to provide 10,000 cells/ml was aseptically introduced into

each flask. The inoculum volume was 1.013 ml per flask. The flasks were shaken manually daily and randomly repositioned each working day to minimize spatial differences in the incubator. Cell counts were performed using an electronic particle counter on test days 3, 4, and 5. Three counts per replicate were made on each counting day.

Temperature in the incubator was automatically measured continuously and manually measured daily. The pH was measured at test initiation (initial test solutions) and at termination (each replicate). Samples were taken at test initiation (initial solutions) and at termination (each replicate) for analysis of the test material by gas chromatography. Samples taken at termination were removed from the supernatant of the solutions after centrifuging for 4 minutes at a speed of 4000 rpm. Samples were frozen and sent to the study sponsor.

E. **Statistics:** The medium and solvent control data were pooled since a t-test indicated no significant difference between the two ($p \leq 0.05$). Percent inhibition of algal growth in the treatment solution was determined by comparison to the growth of the pooled control cultures.

12. **REPORTED RESULTS:** The results from the initial and terminal exposure samples indicated that the test material was present at concentrations of 0.76 and 0.98 mg/l, respectively (Table 3, attached). The results are therefore based on the mean measured concentration of these samples (0.87 mg/l).

Cell counts and percent inhibition after five days are given in Tables 4 and 5 (attached). The test material inhibited the growth of *S. costatum* by 3.8% at a mean measured concentration of 0.87 mg/l.

The pH ranged from 8.02 to 8.05 in the test solution and the controls at test initiation. The pH values on day 5 ranged from 7.65 to 7.70.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors concluded that there is no need for Tier 2 testing because less than 50% inhibition was observed in the test.

Good Laboratory Practice and Quality Assurance statements were included in the report indicating compliance with EPA Good Laboratory Practice Standards, 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedure and the report were generally in accordance with the SEP and Subdivision J guidelines, except for the following deviations:

Cell growth measurements were not taken daily. Measurements were made on days 3, 4, and 5 only.

The results of the temperature measurements were not reported.

The light intensity (2.1 klux) was less than recommended (4 klux).

The photoperiod (14 hours) was less than recommended (16 hours).

B. **Statistical Analysis:** Visual inspection of the percent inhibition of growth in comparison to the pooled control yielded the same result as determined by the authors.

C. **Discussion/Results:** Although the light intensity was one-half of the recommended amount, a 27-fold increase in cellular growth was observed in the pooled control, which indicated that cells were growing logarithmically.

This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a mean measured concentration of 0.87 mg ai/l inhibited the growth of *S. costatum* by 3.8% over the 5-day test period.

D. **Adequacy of the Study:**

(1) Classification: Core.

(2) Rationale: N/A.

(3) Repairability: N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 9-18-92.

RIN 5715-93

VINCLOZOLIN EEB REVIEWS

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____ Information about a pending registration action.

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DATA EVALUATION RECORD

1. **CHEMICAL:** Vinclozolin.
Shaughnessey No. 113201.

2. **TEST MATERIAL:** Vinclozolin (BAS 352 F); 3-(3,5-dichlorophenyl)-5-ethenyl-5-methyl-2,4-oxazolidinedione; CAS No. 50471-44-8; Lot No. N176; 98% active ingredient; a white powder.

3. **STUDY TYPE:** 122-2. Growth and Reproduction of Aquatic Plants - Tier 1. Species Tested: *Lemna gibba*.

4. **CITATION:** Alexander, M.M. and J.S. Hughes. 1992. The Toxicity of Vinclozolin (BAS 352 F) to *Lemna gibba* G3. Laboratory Project ID No. B445-12-5. Conducted by Malcolm Pirnie, Inc., Tarrytown, NY. Submitted by BASF Corporation, Agricultural Chemicals, Research Triangle Park, NC. EPA MRID No. 423947-05.

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Signature: Henry T. Craven 11/3/92
Date: Tracy L. Perry 10/29/92

7. **CONCLUSIONS:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a mean measured concentration of 0.90 mg ai/l stimulated the growth of *L. gibba* by 7.9% over the 14-day test period.

8. **RECOMMENDATIONS:** N/A.

9. **BACKGROUND:**

10. **DISCUSSION OF INDIVIDUAL TESTS:** N/A.

11. **MATERIALS AND METHODS:**

A. **Test Species:** *Lemna gibba* G3 used in the test came from laboratory stock cultures originally obtained from the Horticultural Crops Quality Laboratory, Beltsville, MD. Stock cultures were maintained in synthetic twenty-strength algal assay procedure nutrient medium (20X-AAP) under 4198-5813 lux illumination, and a temperature of 25 ±2°C. Transfers were made to provide 7 to 11 day old cultures. The culture used as inoculum in this test had been transferred to fresh medium nine days before test initiation.

B. **Test System:** All glassware was cleaned according to EPA methods and autoclaved before use. Test vessels used were 500-ml Erlenmeyer flasks fitted with foam stoppers which permitted gas exchange. The test medium was the same as that used for culturing with the pH adjusted to 7.5 ±0.1 and filter sterilized (0.22 µm).

The test vessels were kept in an incubator with environmental conditions like those employed in culturing and continuous warm-white fluorescent illumination.

A 5 mg active ingredient (ai)/ml stock solution was prepared by diluting 51 mg of the test material to 10 ml with dimethylformamide (DMF). The test solution was created by addition of an appropriate volume of the stock (0.2 ml) to 1 l of nutrient medium. The solvent control contained 0.2 ml of DMF/l of nutrient medium.

C. **Dosage:** Fourteen-day growth and reproduction test. One nominal concentration of 1.0 mg ai/l, and a solvent and medium control were selected for the definitive test. The maximum application concentration was reported to be 735 µg/l if applied to a six-inch water column.

D. **Test Design:** Two-hundred ml of the appropriate test or control solution were placed into each of three replicate flasks (3 per treatment level and the controls). A blank (not inoculated) test solution was also prepared to determine stability at test termination.

An inoculum of *Lemna gibba* consisted of three plants per flask, each with four fronds. The flasks were

randomly repositioned each working day to minimize spatial differences in the incubator. Frond counts were performed on test days 2, 5, 7, 9, 12, and 14. Every frond that visibly projected beyond the edge of the parent frond was counted and counting was done at approximately the same time each counting day.

Temperature in the incubator was automatically measured continuously and manually measured daily. The pH was measured at test initiation (initial test solutions). Samples were taken at test initiation (initial solutions) and at termination (each replicate) for analysis of the test material by gas chromatography. Samples were frozen and sent to the study sponsor.

E. **Statistics:** The medium and solvent control data were not pooled since a t-test indicated a significant difference between the two ($p \leq 0.05$). Percent inhibition of frond production in the treatment solution was determined by comparison to the frond growth of the solvent control cultures.

12. **REPORTED RESULTS:** The results from the initial and terminal exposure samples indicated that the test material was present at a concentration of 0.90 mg/l (Table 3, attached). The results are based on the mean measured concentration.

Frond counts and percent inhibition after fourteen days are given in Tables 4 and 5 (attached). Compared to the solvent control, the test material stimulated the growth of *L. gibba* by 7.9% at a mean measured concentration of 0.90 mg/l.

The pH ranged from 7.68 to 7.92 in the test solution and the controls at test initiation.

13. **STUDY AUTHOR'S CONCLUSIONS/QUALITY ASSURANCE MEASURES:** The authors concluded that there is no need for Tier 2 testing because less than 50% inhibition was observed in the test.

Good Laboratory Practice and Quality Assurance statements were included in the report indicating compliance with EPA Good Laboratory Practice Standards, 40 CFR Part 160.

14. **REVIEWER'S DISCUSSION AND INTERPRETATION OF STUDY RESULTS:**

A. **Test Procedure:** The test procedure and the report were generally in accordance with the SEP and Subdivision J guidelines, except for the following deviations:

The results of the temperature measurements were not reported.

The light intensity (4.2-5.8 klux) was occasionally lower or higher than recommended (5 klux).

Three plants with four fronds each were used as the inoculum rather than the recommended five plants with 3 fronds each.

B. **Statistical Analysis:** Visual inspection of the percent inhibition of growth in comparison to the solvent control yielded the same result as determined by the authors.

C. **Discussion/Results:** This study is scientifically sound and meets the guideline requirements for a Tier 1 non-target aquatic plant study. Vinclozolin at a mean measured concentration of 0.90 mg ai/l stimulated the growth of L. gibba by 7.9% over the 14-day test period.

D. **Adequacy of the Study:**

(1) **Classification:** Core.

(2) **Rationale:** N/A.

(3) **Repairability:** N/A.

15. **COMPLETION OF ONE-LINER:** Yes, 9-18-92.

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